State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

EDMUND G. BROWN JR.
Governor

Information Notice

February 8, 2011

To: Radioactive Materials Licensees

Subject: Adoption of Title 10, Code of Federal Regulations, Part 35 (10 CFR 35)

To maintain compatibility with the US Nuclear Regulatory Commission (NRC) and other Agreement States that have adopted 10 CFR 35, the California Department of Public Health (CDPH) has adopted 10 CFR 35, as published January 1, 2008, with minor exceptions. These exceptions can be found in the final approved rule (DPH-05-018) at: http://www.cdph.ca.gov/services/DPOPP/regs/Documents/DPH-05-018%20Final%20Reg%20Text.pdf.

The adoption of these regulations has been approved by the Office of Administrative Law, with an effective date of January 1, 2011. A copy of 10 CFR 35 (January 1, 2008), is available at: http://www.access.gpo.gov/nara/cfr/waisidx_08/10cfr35_08.html.

This Information Notice is the fifth in a series of Information Notices designed to inform licensees of changes which will occur as a result of the adoption of 10 CFR 35, and also how the Radiologic Health Branch (RHB) expects licensees to respond to the changes. Information Notices such as this, as well as relevant NRC generic communications pertaining to 10 CFR Part 35, are posted on the RHB's Radioactive Materials Licensing webpage at: http://www.cdph.ca.gov/certlic/radquip/Pages/RHB-RML-MedicalUse.aspx

The following information is provided to specifically note changes and clarifications regarding the new regulations that licensees may find applicable to their operations and radiation safety programs.

- **Temporary Radiation Safety Officer (RSO)**: 10 CFR 35.24 (c) authorizes that for up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer (RSO) to function as a temporary RSO. To clarify, this section authorizes qualified individuals to function as temporary RSOs for a maximum of 60 days in a calendar year. A licensee choosing to permit temporary RSOs must document and retain for inspection that the individual(s) meet the regulatory requirements to be RSO. Licensees are also required

To establish and retain documentation of the duties and responsibilities of the Radiation Safety Officer and delegation of authority for designated temporary RSOs. A copy of the Duties and Responsibilities of the Radiation Safety Officer and Delegation of Authority need not be submitted to the RHB, but shall be retained by the licensee in their records.

- **Alternate or Assistant Radiation Safety Officer (ARSO)**: The regulations do not address authorization of an ARSO. A licensee may choose to establish an ARSO as part of the internal structure of their radiation safety program, and assign or delegate radiation safety program tasks and duties to the ARSO. However, the RSO designated on the license retains overall responsibility for the radiation protection program, including those functions performed by an ARSO. An ARSO may not be appointed the temporary or permanent RSO unless the individual meets the regulatory requirements to be RSO. Furthermore, RHB expects to correspond with the RSO and not the ARSO with respect to licensing issues.

- **Radiopharmacy Evaluation of License Authorizations:** It will take several months for medical licenses to be converted to the new Part 35 format. Until a license is reformatted, the old format and authorizations under the license are valid. Radiopharmacies will have the authorization to fill orders for radiopharmaceuticals from licensees who have not yet had their license reformatted using the same procedures used prior to the adoption of 10 CFR 35. Please contact RHB for guidance if a license is encountered after January 1, 2012 that has not been reformatted.

- **Workshop Presentations, Frequently Asked Questions (FAQ's) and Forms**: The PowerPoint slides for the workshop presentations held in early December, 2010, as well as FAQ's and new training and experience forms are available on the RHB website at: http://www.cdph.ca.gov/certlic/radquip/Pages/RHB-RML-MedicalUse.aspx.

- **Locum Tenens**: Medical licenses have been modified to include a license condition which allows the licensee to allow a physician to use licensed materials for human use under the terms of the license without receiving an amended license for a period not to exceed 60 days in any calendar year. The physician must meet the specific criteria, and the licensee must maintain records, as outlined in the license condition.

- **Enforcement**: Because of the significant changes to the regulation of medical programs imposed by CDPH's adoption of 10 CFR 35, enforcement discretion will be used by CDPH inspectors for one year from the January 1, 2011 implementation date. During this one-year period, violations of the newly imposed regulatory requirements will not be issued as long as licensees have made a good faith effort to implement the new regulatory requirements without unreasonable delay. This enforcement discretion will not be utilized for 10 CFR 35 requirements that are essentially unchanged from previous requirements.

- **Broad Scope Licensees and Authorized User Requirements**: Broad scope licensees must follow the training and experience requirements for the RSO, Authorized Medical Physicist (AMP), Authorized Nuclear Pharmacist (ANP), and Authorized User (AU) as provided in the newly adopted 10 CFR 35 (2008 Edition) regulations (10 CFR 35.50, 35.51, 35.5, 35.57, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, and 35.690). These training and experience requirements must be met by broad scope licensees for internal approvals of AMPs, ANPs or AUs.

- **Patient Release Criteria**: 10 CFR 35.75 addresses the release of individuals containing unsealed byproduct material or implants containing byproduct material. The licensee should refer to the guidance provided in NUREG 1556 Volume 9 (Rev 2), Appendix U to determine and document whether or not a patient may be released from the licensee's control. In addition to the guidance in NUREG 1556, licensees may utilize other recognized methods or computer calculation programs such as RADAR (available at www.doseinfo-radar.com); however, the use of other methods in lieu of NUREG 1556 must be sufficiently documented if values used differ from NUREG 1556 values.

  Please note that, while not expressly prohibited, discharge of patients under 35.75 to hotels/motels is strongly discouraged by NRC and CDPH because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses which are not ALARA. More information about this subject can be found in NRC Regulatory Issue Summary 2011-01 - NRC Policy On Release Of Iodine-131 Therapy Patients Under 10 CFR 35.75 To Locations Other Than Private Residences at: www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2011//index.html.

Also, licensees who discharge patients under 10 CFR 35.75 to residences shared with young children or pregnant females may choose to encourage such patients to temporarily relocate these young children and pregnant females to alternative locations, or to consider not releasing such patients. More information about this subject can be found in NRC Regulatory Issue Summary 2008-11 - Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration Of Iodine-131 at: www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2008//index.html .

If you have any questions or comments, please contact Ira Schneider by telephone at (916) 440-7976 or by email at Ira.Schneider@cdph.ca.gov.

Sincerely,

Original Signed By Ira Schneider

Ira Schneider
Senior Health Physicist
Radiologic Health Branch
(916) 440-7976